NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE AMARIN CORPORATION PLC SECURITIES LITIGATION	Civ. Action No.: 13-6663 (FLW)(TJB) **OPINION**

Presently before the Court is a motion to dismiss the Second Consolidated and Amended Class Action Complaint ("SAC") filed by Lead Plaintiff James L. Reiss ("Plaintiff") against Defendants Amarin Corporation PLC ("Amarin" or the "Company"), Amarin's former CEO and Chairman of Amarin's Board of Directors (the "Board"), Joseph S. Zakrzewski ("Zakrzewski"), Amarin's current CEO and Chairman of the Board, John F. Thero ("Thero"), and Amarin's current Senior Vice President and President of Research and Development, Steven B. Ketchum ("Ketchum") (Zakrzewski, Thero, and Ketchum known collectively as the "Individual Defendants") (Amarin and the Individual Defendants known collectively as "Defendants"). Plaintiff's claims arise from alleged misrepresentations Defendants made regarding the progress of Amarin's ultimately unsuccessful application to the FDA to approve its drug, Vascepa, for the treatment of patients with high triglyceride levels. Plaintiff, as an Amarin shareholder, asserts claims against Defendants under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5, promulgated thereunder ("Rule 10b-5"), as well as pursuant to Section 20(a) of the Exchange Act.

For the reasons set forth below, Defendants' motion to dismiss is granted. Plaintiff's Complaint is dismissed without prejudice.

I. Procedural and Factual Background

The following allegations are taken from the SAC and are assumed as true for the purposes of review under Rule 12(b)(6). Amarin is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. SAC ¶ 62. Vascepa is Amarin's primary product and, according to Amarin's SEC filings, "is an ultra-pure, EPA [ethyl eicosapentaenoic acid] -only omega-3 fatty acid product" for the treatment of patients with very high and high triglycerides. SAC ¶ 73.

During the period from November 29, 2010 through October 16, 2013 (the "Class Period"), Amarin sought FDA approval to market Vascepa to patients with high triglyceride ("TG") levels (TG levels between 200 and 500 mg/dL) and mixed dyslipidemia, who were currently on statin therapy,[1] for use adjunct to diet and exercise (a treatment purpose known as the ANCHOR indication).[2] SAC ¶¶ 16, 18. In support of this application, Amarin completed a 12-week Phase III registration trial (the "ANCHOR study"), which was designed "to determine if administration of Vascepa to the patient population already optimized on statin therapy reduced TGs." SAC ¶¶ 16, 30. Because the ANCHOR study was a shorter-term trial, it utilized a surrogate endpoint, meaning it was based on a hypothesis that reducing TGs in patients, when co-administered with statins, would lead to a statistically significant reduction in major adverse cardiac events ("MACE"). SAC

[1] According to Plaintiff, "[s]tatins are a class of drugs that work in the liver to prevent the formation of LDL (bad) cholesterol, thus lowering the amount of cholesterol circulating in the blood. Statins are most effective at lowering LDL (bad) cholesterol, but also have modest effects on lowering triglycerides (blood fats) and raising HDL (good) cholesterol." SAC at viii. By comparison, Vascepa's primary intended effect is to lower triglyceride levels. SAC ¶ 73.

[2] During the Class Period, Amarin also applied for and received approval from the FDA to market Vascepa as a treatment for patients with severe hypertriglyceridemia (TG levels above 500 mg/dL), when administered adjunct to diet (a treatment purpose known as the MARINE indication). SAC at vii-viii.

at vi, ¶¶ 18. By contrast, a study directly investigating the primary endpoint of Vascepa's effect on MACE, when co-administered with statins, would require a long-term outcomes trial tracking "survival benefit." SAC at vi. According to Plaintiff, "Amarin's future profitability throughout the Class Period was dependent on obtaining FDA approval to market Vascepa based on the ANCHOR study without first being required to conduct a long-term outcomes study."[3] SAC ¶ 35.

In July 2008, senior officers of Amarin met with the FDA (the "2008 Meeting") to determine whether the current design of the ANCHOR study was "adequate to provide the clinical efficacy data necessary to support the proposed [ANCHOR] indication."[4] SAC ¶¶ 3, 23 (alteration in original). Plaintiff alleges that at the meeting, the FDA informed Amarin that it "would not commit to approving ANCHOR based only on a surrogate end-point [i.e. the ANCHOR study]," because it was not aware of any prospective, controlled clinical trial data demonstrating that a pharmacological reduction of non-HDL-C (or TGs), in combination with a second drug, in patients with elevated TG Levels at LDL goal on statin therapy, significantly reduces residual cardiovascular risk. SAC ¶ 4. The FDA indicated that three ongoing cardiovascular outcomes trials for different drugs that were also targeted at reducing non-HDL-C (or TGs), AIM-HIGH, ACCORD, and IMPROVE-IT, "while not designed to address the specific gap in knowledge, [would] provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy." SAC ¶ 4. Consequently, the FDA informed Amarin that to receive approval

[3] Previously, in the Consolidated and Amended Class Action Complaint (the "CAC"), Plaintiff alleged unequivocally that "Amarin's *only* prospect for profitability during the Class Period was the approval of Vascepa for the ANCHOR indication." CAC ¶ 8 (emphasis added). However, Plaintiff has since retreated from this position, presumably because during the Class Period, Vascepa was approved by the FDA for the MARINE indication, which would provide an alternative source of profits for Amarin. SAC at vii-viii.

[4] Plaintiff cites to minutes from the 2008 Meeting (the "2008 Minutes").

of Vascepa for the ANCHOR indication, it would, "at a minimum," have to (1) provide the FDA with the results from the ANCHOR study and (2) "initiate an appropriately designed cardiovascular outcomes study" that was "well under way" by the time the FDA reviewed the results from the ANCHOR study. SAC ¶ 21. To address these concerns, on July 6, 2009, Amarin signed a Special Protocol Agreement (the "2009 SPA") with the FDA, which established the agreed design for the ANCHOR study. SAC ¶ 27. According to Plaintiff, the 2009 SPA stated that "notwithstanding whether the ANCHOR protocol achieved its endpoints . . . the CVOT REDUCE-IT study would have to be 50% enrolled before the FDA would consider the ANCHOR sNDA."[5] SAC ¶ 27. On August 5, 2011, the FDA entered into a separate Special Protocol Agreement (the "2011 SPA") with Amarin regarding the design of Amarin's cardiovascular outcomes study, REDUCE-IT. SAC ¶ 32.

In March 2010, the unsuccessful results from the ACCORD study, one of the three long-term cardiovascular outcomes studies that the FDA had identified in the 2008 Meeting as providing "important information," were announced. SAC ¶ 34. In April 2011, Amarin announced the positive results of the ANCHOR study, which showed that Vascepa had a statistically significant favorable effect on TGs, LDL cholesterol, and non-HDL cholesterol. SAC ¶¶ 250-51. In May

[5] Although Plaintiff alleges that the 2009 SPA required that the REDUCE-IT study have "50%" patient enrollment before Vascepa could be considered for the ANCHOR indication, the actual text of the 2009 SPA is completely silent as to an enrollment requirement. *See* Decl. of Allison M. Wuertz in Supp. of Defs.' Mot. to Dismiss the SAC ("Wuertz Decl.") Ex. C. Plaintiff may be referring to the FDA's statement in the 2008 Minutes that "in order to consider granting an indication for add on therapy with statins, there must be an outcomes trial in process with *approximately half* of the patients enrolled when the NDA is submitted." *See id.* Ex. A at 10 (emphasis added). I note that I may properly consider the 2009 SPA and the 2008 Minutes on this motion to dismiss, because these documents are explicitly relied upon in the pleadings. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (A "document integral to or explicitly relied upon in the complaint may be considered without converting the motion [to dismiss] into one for summary judgment." (quotations omitted)).

2011, the unsuccessful results from the AIM-HIGH study, another of the three studies identified by the FDA, were announced.[6] SAC ¶ 34. Likewise, HPS2-THRIVE, another long-term cardiovascular outcomes trial that was not mentioned in the 2008 Meeting, also failed, with the test results announced in December 2012. SAC ¶ 342. By February 26, 2013, REDUCE-IT was "substantially underway," and Amarin announced that it had submitted the supplemental New Drug Application to the FDA for approval of the ANCHOR indication for Vascepa. SAC ¶¶ 347, 352.

On October 16, 2013, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee ("AdCom") rejected the ANCHOR indication for Vascepa, because it found that there was insufficient data to support the use of reducing TGs as a surrogate endpoint for MACE reduction. SAC ¶¶ 383, 399-400. Thus, on October 29, 2013, the FDA rescinded the 2009 SPA, "citing results from the ACCORD, AIM-HIGH- and HPS2-THRIVE CVOT studies as establishing that 'a substantial scientific issue essential to determining the effectiveness of Vascepa in this [high TG] population was identified after testing began.'" SAC ¶ 141.

Plaintiff alleges that during the Class Period (i.e. prior to the FDA's rejection of Amarin's ANCHOR application), Defendants "intentionally failed to inform investors of [1] the connections drawn by the FDA among the three studies (ANCHOR, ACCORD, and AIM-HIGH), and [sic] [2] the FDA's 'uncertainty around the science supporting TG as a surrogate for [cardiovascular] risk,' and [3] the FDA's statement that AIM-HIGH and ACCORD would provide 'important information on the incremental benefit of a second lipid active drug to statin therapy.'" SAC ¶ 38.

[6] Conversely, the IMPROVE-IT study, the third study identified by the FDA in the 2008 Meeting, actually saw modest favorable results. SAC ¶¶ 165-66, 485(v). But these results were not announced until November 17, 2014, well after Amarin's application to the FDA for approval of Vascepa was rejected. SAC ¶¶ 165-66, 485(v).

Additionally, Plaintiff alleges that "Defendants misrepresented facts with respect to the likelihood of obtaining FDA approval for the ANCHOR indication without REDUCE-IT." SAC¶ 39.

Plaintiff further alleges that during the Class Period, Defendants misrepresented that the results of the Japan Eicosapentaenoic Acid ("EPA") Lipid Intervention Study ("JELIS"), a cardiovascular outcomes study of a sister drug to Vascepa, were indicative of the efficacy of Vascepa for the ANCHOR indication. SAC¶ 177. Specifically, Plaintiff alleges that although JELIS indicated that the addition of EPA to statin therapy *does* provide additional benefit in preventing MACE, JELIS is not sufficiently comparable to the ANCHOR study, because the patient population was exclusively Japanese and the trial was open label (both participants and researchers knew which treatment was being administered). SAC¶¶ 168, 171, 180.

Finally, Plaintiff alleges that Defendants misrepresented "facts concerning . . . the use of mineral oil as a placebo in the ANCHOR study." SAC ¶ 44. Specifically, Plaintiff alleges that Defendants did not express concerns raised by Plaintiff's Confidential Witness A ("CWA") and the FDA about the viability of mineral oil as a placebo for the ANCHOR study, because mineral oil "may not be inert." SAC ¶¶ 93-107, 213.

According to Plaintiff, these omissions and misrepresentations were made "to induce Class Members to make in excess of $226 million of investments in Amarin securities through two secondary offerings — on January 6, 2011 — 13.8 million [American Depository Shares ("ADS")] at $7.60 per [share], and on July 10, 2013 - 21.7 million ADS at $5.60 per [share]." SAC ¶ 39. Plaintiff additionally alleges that "Defendants were motivated to commit the fraud because they knew that Amarin was required to raise cash in public offerings to conduct the long-term REDUCE-IT study and that investors would be unwilling to buy Amarin ADS in these public offerings if they knew that Amarin was required to conduct the long-term REDUCE-IT study at

an expense in excess of $100 million to get FDA approval." SAC ¶ 40. Further, "[t]he long-term REDUCE-IT study introduced an element of cost, risk, and delay that would have been unacceptable to public investors." SAC ¶ 41. Plaintiff asserts that due to these omissions and misrepresentations, "and unbeknownst to the investing public, Amarin securities traded at materially inflated prices throughout the Class Period." SAC ¶ 45. Plaintiff further asserts that the Individual Defendants, and other senior Amarin executives, "with knowledge of the undisclosed facts, exercised stock options and sold Amarin ADS to unsuspecting investors on the open market, garnering unlawful profits of excess of $15 million." SAC ¶ 53.

On October 11, 2013, the FDA released its briefing document for the AdCom meeting scheduled for October 16, 2013 (the "Briefing Document"). SAC ¶ 47. According to Plaintiff, the Briefing Document revealed that "Amarin had been informed by the FDA in July 2008 that the FDA's willingness to approve Vascepa for use by a 36 million patient population based only on a 12-week trial, was dependent on the ACCORD and AIM-HIGH test results, and further that those test results had been unsuccessful." SAC ¶ 48. Plaintiff also asserts that "the Briefing Document called into question whether Vascepa offered any meaningful clinical benefit to patients with high triglyceride levels." SAC ¶ 49. Upon the release of the Briefing Document, Amarin's shares declined by $1.28 per share — from $6.37 to $5.09 — over 20% — on volume of over 37.9 million shares. SAC ¶ 51. Plaintiff further asserts that after the release of news that the AdCom had voted against approval of Vascepa for the ANCHOR indication, "Amarin shares declined an additional $3.16 per share — over 61% on volume of over 105.6 million shares." SAC ¶ 51.

On November 1, 2013, Plaintiff filed this lawsuit claiming that Defendants' actions have amounted to securities fraud in violation of Section 10(b) of the Exchange Act and Rule 10b-5, and, moreover, that the Individual Defendants are liable for Amarin's Section 10(b) violations

under Section 20(a) of the Exchange Act. On July 29, 2014, the Court consolidated the various securities actions filed against Amarin into this single case and appointed Plaintiff as Lead Plaintiff. Subsequently, on November 11, 2014, Defendants moved to dismiss the CAC. On June 26, 2015, the Court granted Defendants' motion to dismiss, finding that Plaintiff had failed to allege either (1) that Defendants made a materially false or misleading statement or (2) that Defendants acted with scienter. *In re Amarin Corp. PLC*, Civ. No. 13-6663, 2015 U.S. Dist. LEXIS 84080, at *50, *70 (D.N.J. June 26, 2015). The Court granted Plaintiff leave to amend the CAC within thirty days. *Id.* at *70. Thereafter, Plaintiff filed the SAC.

Plaintiff alleges new facts in the SAC in an attempt to cure the deficiencies previously identified by the Court.[7] Regarding the importance of the ACCORD and AIM-HIGH studies, Plaintiff newly alleges that Defendants misrepresented the significance of these studies to Amarin's application for the ANCHOR indication. SAC ¶¶ 124(a)-(e), 361, 381. Additionally, the SAC contains new allegations that in the 2009 SPA, "the FDA informed Amarin that it would not commit to approve Vascepa for the ANCHOR indication, based only on the 12-week test of surrogate endpoints, and the commencement of the REDUCE-IT outcomes study," but instead specified that "approval would be 'a review issue.'" SAC ¶ 10(b). Plaintiff also newly alleges that Defendants misrepresented that (1) lower TG levels was an accepted surrogate for long-term MACE outcomes studies and (2) the failure of the ACCORD and AIM-HIGH studies were positive developments for Amarin because they reduced competition. SAC ¶ 10(g). Regarding the JELIS study, in the same vein as his previous allegations, Plaintiff includes new allegations regarding

[7] These new allegations are in part based on declarations and exhibits in a litigation filed by Amarin, on May 7, 2015, against the FDA in the U.S. District Court for the Southern District of New York (15-cv-03588) (the "NY Action"). SAC ¶¶ 2, 10(a).

additional misleading statements made by Defendants about JELIS and alleges that Defendants later corrected their materially false and misleading statements in Amarin's 2013 fiscal form 10-K. SAC ¶¶ 180, 292, 361, 381. Regarding the use of mineral oil as a placebo, Plaintiff alleges very limited new facts, which are intended to bolster allegations that the FDA had explicitly expressed concerns to Defendants that the use of mineral oil would severely jeopardize Amarin's ANCHOR application. SAC ¶¶104-105. However, Plaintiff admits in his brief that "these allegations are not likely to be sufficient for this Court to reconsider its Opinion with respect to mineral oil." Mem. of Law in Opp'n to Defs.' Mot. to Dismiss the SAC ("Pl.'s Opp'n Br.") 4 n. 5. Finally, Plaintiff newly alleges that Defendants made other materially false or misleading claims (1) that positive ANCHOR results will stimulate additional interest from commercial partners; (2) that Vascepa was designed to be first-in-class for the treatment of high TGs; and (3) regarding the size of the anticipated market for the ANCHOR indication.

Additionally, Plaintiff alleges new facts to address the Court's previous finding that the CAC did not contain sufficient facts to give rise to a strong inference that Defendants had the necessary scienter to violate Section 10(b). *See In re Amarin*¸ 2015 U.S. Dist. LEXIS 84080, at *51-70. Regarding scienter, the Court previously found that the CAC failed, *inter alia*, (1) to identify any suspicious stock sales by Amarin's executives; (2) to allege a motive, beyond the generic corporate motive to continue Amarin's success; and (3) to allege that the Individual Defendants had the necessary knowledge to make a consciously or recklessly false statement. *Id* The Court concluded that taken as a whole, the most plausible inference that could be made based upon the allegations in the CAC was that "at most, Amarin executives were simply overly optimistic about the success of the ANCHOR study and the likelihood of FDA approval for the ANCHOR indication," rather than intent on defrauding investors. *Id.* at *68-70.

In an attempt to cure these deficiencies, Plaintiff alleges in the SAC (1) additional facts indicating that Amarin was aware of the FDA's concerns regarding the use of surrogate endpoints and the ACCORD and AIM-HIGH studies, SAC ¶¶ 130, 132-39, 142-43; (2) that Declan Doogan ("Doogan"), a senior Amarin officer, was present at the 2008 Meeting, and therefore had personal knowledge of the FDA's warnings regarding the importance of the ACCORD and AIM-HIGH studies, SAC ¶¶ 10(i), 23-24, 122, 124(a), 124(c), 185, 190-96, 214-15, 243, 428; and (3) that Zakrzewski and Thero, as Amarin senior officers in August 2011, when the 2011 SPA was finalized, had actual knowledge that "that approval of the ANCHOR indication, notwithstanding ANCHOR's ability to achieve efficacy based on surrogate endpoints . . . was likely to require completion of the REDUCE-IT trial particularly in light of the failure of ACCORD and AIM-HIGH," SAC ¶ 34.

Defendants move to dismiss the SAC, asserting that Plaintiff has again failed to allege that (1) Defendants made a material misrepresentation or misleading statement or (2) facts to support a strong inference that Defendants acted with scienter. Additionally, Defendants argue that the SAC should be dismissed pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), the truth-on-the-market doctrine, and because the majority of the challenged statements are inactionable corporate puffery. Plaintiff opposes Defendants' motion.

II. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), a complaint may be dismissed for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the

complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (quotations omitted). Under such a standard, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Indeed, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[A] complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009).

However, Rule 12(b)(6) only requires a "short and plain statement of the claim showing that the pleader is entitled to relief" in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. The complaint must include "enough factual matter (taken as true) to suggest the required element. This does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips*, 515 F.3d at 234 (citation and quotations omitted); *Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) ("[A] claimant does not have to set out in detail the facts upon which he bases his claim. The pleading standard is not akin to a probability requirement; to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief." (citation and quotations omitted)).

In sum, under the current pleading regime, when a court considers a dismissal motion, three sequential steps must be taken: first, "it must take note of the elements the plaintiff must plead to state a claim." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quotations omitted). Next, the court "should identify allegations that, because they are no more than

conclusions, are not entitled to the assumption of truth." *Id.* (quotations omitted). Lastly, "when there are well-pleaded factual allegations, the court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* (quotations and brackets omitted).

"Independent of the standard applicable to Rule 12(b)(6) motions," Fed. R. Civ. P. 9(b) "imposes a heightened pleading requirement of factual particularity with respect to allegations of fraud." *In re Rockefeller Ctr. Props. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002); *see also* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."). To satisfy this heightened pleading standard, a plaintiff must state the circumstances of his alleged cause of action with "sufficient particularity to place the defendant on notice of the 'precise misconduct with which [it is] charged.'" *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (quoting *Lum v. Bank of America*, 361 F.3d 217, 223-24 (3d Cir. 2004)). Specifically, the plaintiff must plead or allege the "date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico*, 507 F.3d at 200 (citing *Lum*, 361 F.3d at 224). Indeed, the Third Circuit has advised that, at a minimum, Rule 9(b) requires a plaintiff to allege the "essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276-77 (3d Cir. 2006) (quoting *In re Rockefeller*, 311 F.3d at 216).

In addition to Rule 9(b)'s heightened pleading requirements, Congress enacted the PSLRA, 15 U.S.C § 78u *et seq.*, to require an even higher pleading standard for plaintiffs bringing private securities fraud actions. *In re Suprema*, 438 F.3d at 276. This heightened pleading standard is

targeted at preventing abusive securities litigation. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) ("Private securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law."); *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006) (identifying "ways in which the class-action device was being used to injure the entire U.S. economy" and listing examples such as "nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests, and manipulation by class action lawyers of the clients whom they purportedly represent . . .") (quotes and citations omitted).

The PSLRA provides two distinct pleading requirements, both of which must be met in order for a complaint to survive a motion to dismiss. *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009). First, under 15 U.S.C. § 78u-4(b)(1), the complaint must "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Winer Family Trust v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007) (construing 15 U.S.C. § 78u-4(b)(1)). Second, the complaint must, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).[8]

[8] The PSLRA states, in pertinent part:

> (b) Requirements for securities fraud actions
> (1) Misleading statements and omissions
> In any private action arising under this chapter in which the plaintiff alleges that the defendant-
> (A) made an untrue statement of a material fact; or
> (B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading; the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an

Both provisions of the PSLRA require facts to be pled with "particularity." *Avaya*, 564 F.3d at 253. This particularity language "echoes precisely Fed. R. Civ. P. 9(b)." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999); *see* Fed. R. Civ. P. 9(b) ("[A] party must state with particularity the circumstances constituting fraud or mistake."). Indeed, although the PSLRA replaces Rule 9(b) as the pleading standard governing private securities class actions, the rule's particularity requirement "is comparable to and effectively subsumed by the requirements of [§ 78u-4(b)(1) of] the PSLRA." *Avaya*, 564 F.3d at 253 (citations omitted). This standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *In re Advanta*, 180 F.3d at 534 (quotations marks omitted).

III. Analysis

A. Claims under Section 10(b) of the Exchange Act

The private right of action under Section 10(b) and Rule 10b-5 "creates liability for false or misleading statements or omissions of material fact that affect trading on the secondary market." *Burlington*, 114 F.3d at 1417. In relevant part, Rule 10b-5 makes it unlawful for an individual "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not

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> allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.
>
> (2) Required state of mind
>
> In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

15 U.S.C.A. § 78u-4(b)(1), (2).

misleading . . . in connection with the purchase or sale of any security.'" 17 C.F.R. § 240.10b-5(b). To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5, the plaintiff must allege: "(1) a material misrepresentation or omission, (2) scienter, (3) a connection with the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation." *Gold v. Ford Motor Co.*, 577 F. App'x 120, 122 (3d Cir. 2014) (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)).

Here, Defendants argue, among other things, that Plaintiff fails to state a claim for securities fraud because Plaintiff does not sufficiently allege that Defendants (1) made a materially false or misleading statement or (2) acted with scienter. Under Section 10(b) and Rule 10b-5, a misrepresentation or omission of fact is material "if there is a substantial likelihood that a reasonable shareholder would consider it important" in making an investment decision, and there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (quoting *TSC Indus. v. Northway*, 426 U.S. 438, 440, 449 (1976)); *see also Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000). Importantly, to be actionable, a statement or omission must have been materially misleading at the time it was made; liability cannot be imposed on the basis of subsequent events. *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002).

Additionally, because materiality is a mixed question of law and fact, "[o]nly if the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality is it appropriate for the district court to rule that the allegations are inactionable as a matter of law." *Shapiro v. UJB Financial Corp.*, 964 F.2d 272, 280 n. 11 (3d Cir. 1992) (citation omitted). The Third Circuit has warned that the task of

determining materiality can be especially difficult when the statement at issue contains "soft" information, i.e. statements of subjective analysis or extrapolation, such as opinions, motives, and intentions, or forward looking statements, such as projections, estimates, and forecasts. *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 642 (3d Cir. 1989)

However, regardless of whether a piece of information is material, Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Indeed, "[s]ilence, absent a duty to disclose, is not misleading under Rule 10b-5." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014) (quoting *Basic*, 485 U.S. at 239 n. 17). Rather, "[d]isclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b-5(b)); *see also City of Edinburgh*, 754 F.3d at 174; *Burlington*, 114 F.3d at 1432 (3d Cir. 1997) ("[P]ossession of material nonpublic information alone does not create a duty to disclose it.").

Additionally, according to the Supreme Court's opinion in *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, when the alleged misleading statement at issue is an opinion or a belief, whether that statement is 'misleading' "depends on the perspective of a reasonable investor: The inquiry (like the one into materiality) is objective." 135 S. Ct. 1318, 1327 (2015). Although the Supreme Court in *Omnicare* examined claims under Section 11 of the Securities Act of 1933, these principles are "not unique to §11." *Id.* at 1330. Rather, "[t]hey inhere, too, in much common law respecting the tort of misrepresentation," *Id.*, and are therefore arguably applicable to claims under Section 10(b) as well. *See In re Merck & Co.*, Civ. No. 1658, 2015 U.S. Dist. LEXIS 62983, at *65 n. 7 (D.N.J. May 13, 2015) (finding *Omnicare's* analysis of misleading

opinions, instructive, to some extent, on the viability of claims regarding misleading opinions under Section 10(b)). As the Supreme Court observed in *Omnicare*:

> The Restatement of Torts, for example, recognizes that "[a] statement of opinion as to facts not disclosed and not otherwise known to the recipient may" in some circumstances reasonably "be interpreted by him as an implied statement" that the speaker "knows facts sufficient to justify him in forming" the opinion, or that he at least knows no facts "incompatible with [the] opinion." When that is so, the Restatement explains, liability may result from omission of facts—for example, the fact that the speaker failed to conduct any investigation—that rebut the recipient's predictable inference.

Omnicare, 135 S. Ct. at 1330 (quoting Restatement (Second) of Torts § 539 at 85, Comment a at 86, Comment b at 87 (1976) (citations omitted)). These principles square with the Third Circuit's admonition that when evaluating Section 10(b) claims, courts must examine allegedly misleading statements in context, to determine whether they were indeed misleading. *See City of Edinburgh*, 754 F.3d at 167. Furthermore, the Third Circuit has conclusively ruled that "[o]pinions are only actionable under securities laws[, including Section 10(b),] if they are not honestly believed and lack a reasonable basis." *Id.* at 170.

Similarly, under the PSLRA, "forward-looking" statements are not actionable if they are "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna Sec. Litig.*, 617 F.3d 272, 278-79 (3d Cir. 2010). The PSLRA's definition of "forward-looking statement" includes, *inter alia*, "projections of future performance, plans and objectives for future operations, and assumptions underlying statements about future financial, economic or operational performance." *Id.* at 279 (citing 15 U.S.C. § 78u-5(i)(1)). This safe harbor for forward-looking statements overlaps with the Third Circuit's "bespeaks caution" doctrine, adopted in *In re Trump*, 7 F.3d 357 (3d Cir. 1993). Under this doctrine, "cautionary language, if sufficient, renders the

alleged [forward-looking] omissions or misrepresentations immaterial as a matter of law." *Id.* at 371. Under both the PSLRA and the bespeaks caution doctrine, cautionary language must be extensive, specific, and directly related to the alleged misrepresentation to provide a safe harbor. *See In re Aetna*, 617 F.3d at 282; *Id.* at 371-72.

In addition, like forward-looking statements, opinions, and beliefs, a defendant may not be held liable for an alleged misrepresentation that consists of nothing more than vague and non-specific expressions of corporate optimism. *In re Advanta*, 180 F.3d at 538. Such statements "constitute no more than 'puffery' and are understood by reasonable investors as such." *Id.* (quoting *Burlington*, 114 F.3d at 1428 n. 14). Thus, if a false or misleading statement is "too vague to ascertain anything on which a reasonable investor might rely," it is inactionable as corporate puffery. *In re Aetna*, 617 F.3d at 284.

Here, Defendants argue that Plaintiff has failed to allege that Defendants made a materially false or misleading statement. In the SAC, Plaintiff asserts that Defendants made multiple sets of materially false or misleading statements, including (1) statements that it was not necessary to complete the REDUCE-IT study to receive the ANCHOR indication, SAC ¶¶ 209(i), 209(ii); (2) statements regarding the required REDUCE-IT study enrollment levels to file the ANCHOR sNDA, SAC ¶ 434; (3) statements regarding the JELIS trial, SAC ¶ 44; (4) statements regarding the importance of the ACCORD and AIM-HIGH studies, SAC ¶ 209(v); (5) statements regarding the use of TG levels as a surrogate endpoint, SAC ¶¶ 209(iii), 209(iv); (6) statements regarding the mineral oil placebo in the ANCHOR study, SAC ¶ 44; (7) claims that positive ANCHOR results would stimulate additional interest from commercial partners, SAC ¶ 209(vii); (8) claims that Vascepa was designed to be first-in-class for the treatment of high TGs, SAC ¶ 209(vi); and

(9) statements regarding the size of the anticipated market for the ANCHOR indication, SAC ¶ 209(viii). The Court will examine each set of allegedly false and misleading statements in turn.

i. Claims That It Is Not Necessary to Complete the REDUCE-IT Study to Receive the ANCHOR indication

First, Plaintiff re-alleges that it was materially false and misleading for Defendants to make public statements "that the results of a CV outcomes study was not required for FDA approval of the ANCHOR indication." SAC ¶ 11. I previously found in the June 26, 2015 Opinion that Plaintiff had failed to sufficiently allege that such statements were materially false and misleading, because the CAC contained no allegations that the FDA had expressly informed Amarin, prior to its application for the ANCHOR indication, that completing the REDUCE-IT study was necessary to attain the indication. *See In re Amarin*, 2015 U.S. Dist. LEXIS 84080, at *30. Instead, under the facts alleged in the CAC, the FDA only stated that before the ANCHOR indication could be considered for Vascepa, Amarin "would have to provide results from a 12-week study with lipid endpoints[, the ANCHOR study,] as well as initiate an appropriately designed cardiovascular outcomes study[, the REDUCE-IT study]." CAC ¶ 13. Thus, the Court previously concluded that Defendants' statements claiming that the FDA required the ANCHOR study results, but not the REDUCE-IT study results, to receive approval for the ANCHOR indication, were not misleading, because they accurately stated the FDA's position. *In re Amarin*, 2015 U.S. Dist. LEXIS 84080, at *21 n. 8, 30.

Presently, Plaintiff attempts to address these deficiencies with new allegations that in 2009, "the FDA informed Amarin that it would not commit to approve Vascepa for the ANCHOR indication, based only on the 12-week test of surrogate endpoints, and the commencement of the REDUCE-IT outcomes study," but instead specified that "approval would be 'a review issue.'"

SAC ¶ 10(b). In the 2009 SPA, Amarin asked the FDA, among other things, whether successful results in the ANCHOR study would "provide an adequate basis for approval for the indication." SAC ¶ 127. When the FDA responded "[t]his is a review issue," Plaintiff contends that in actuality "the FDA answered (in essence) 'no.'" SAC ¶¶ 33, 128. In addition, Plaintiff alleges that the FDA's "review issue" language "clearly related to its earlier advice to Amarin of the implication of AIM-HIGH and ACCORD on the ANCHOR sNDA." SAC ¶ 279. Therefore, Plaintiff contends that because Defendants were informed by the FDA that this matter was a "review issue," Defendants' claims that the completion of the REDUCE-IT study was not necessary to receive the ANCHOR indication were materially misleading.[9] SAC ¶¶ 10(b), 27, 33, 34, 127, 137, 138, 209(i), 278, 279.

However, the Court does not agree with Plaintiff's interpretation of the phrase "review issue." When directly asked whether successful results in the ANCHOR study would provide an adequate basis for approval for the ANCHOR indication, the FDA did not answer "no." Rather, the use of the language "review issue" implies that it is possible, although not guaranteed, that this would be an adequate basis for approval. It does not indicate, as Plaintiff contends, that "given the failure of the ACCORD and AIM-HIGH trials, [the REDUCE-IT results] were almost certainly going to be required by the FDA prior to approval of ANCHOR." SAC ¶ 209(i). Indeed, if the FDA had wished to make the REDUCE-IT study results a prerequisite to approval for the ANCHOR indication, they could have expressly included those terms in the 2009 SPA. Importantly, Plaintiff does not allege that Defendants claimed that fulfillment of the 2009 SPA

[9] Additionally, Plaintiff alleges that "[t]hereafter, in an SPA dated August 5, 2011, the FDA reiterated that it would not commit to approve Vascepa for the ANCHOR indication, even if REDUCE-IT was substantially underway, but that approval would be a 'review issue.'" SAC ¶ 10(b); *see also* SAC ¶¶ 32-33.

terms would guarantee approval of the ANCHOR indication. Rather, under the facts alleged, Defendants accurately stated the position of the FDA as expressed to them — that the results of the REDUCE-IT study were not a prerequisite to approval for the ANCHOR indication.

Plaintiff also reasserts its argument, previously dismissed in the June 26, 2015 Opinion, that "Defendants failed to disclose facts necessary to make these statements made [sic] not materially false and misleading." However, taking the facts alleged as a whole, Defendants' statements regarding the necessity of completing the REDUCE-IT study for approval of the ANCHOR indication were not misleading. These statements merely accurately reflected the agreed terms of the 2008 Meeting and the 2009 SPA. Thus, as explained in the June 26, 2015 Opinion, Defendants did not have a duty to disclose the FDA's comments from the 2008 Meeting regarding the importance of the AIM-HIGH and ACCORD studies. Likewise, Defendants did not have a duty to disclose the fact that the FDA considered the approval of the ANCHOR indication a "review issue." *See Oran*, 226 F.3d at 285 (finding that the defendant "did not make any 'affirmative characterization' that the FDA's approval was based on a complete review of every piece of relevant medical information . . . . [but r]ather . . . made a simple (and accurate) factual assertion that the FDA had found that Redux had an 'acceptable safety profile' following a 'thorough review of more than 17 clinical trials'"); *The Winer Family Trust v. Queen*, No. Civ. No. 03-4318, 2004 U.S. Dist. LEXIS 19244, at *7 (E.D. Pa. Sept. 27, 2004) *aff'd sub nom. Winer Family Trust v. Queen*, 503 F.3d 319 (3d Cir. 2007) ("Rule 10b-5 . . . prohibits only misleading and untrue statements, not statements that are incomplete. Often, a statement will not mislead even if it is incomplete or does not include all relevant facts.") (quoting *Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)); *cf. In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Mere questioning by the FDA imposed no duty upon Defendants either

to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers' questions as they arose.").

In sum, Plaintiff has failed to allege that this first set of statements were materially false or misleading, thus, these statements do not support a Rule 10b-5 action.

ii. Statements Regarding the Required REDUCE-IT Study Enrollment Levels to File the ANCHOR sNDA

Plaintiff alleges that "even though the 2008 Minutes and 2009 SPA clearly required that REDUCE-IT be at least 50% enrolled before the FDA accepted the ANCHOR sNDA for filing, Zakrzewski dissembled the truth and told investors that Amarin was negotiating with the FDA to require that REDUCE-IT be only 25% enrolled prior to submitting the sNDA." SAC ¶ 262. Specifically, Plaintiff points to the following comment made by Zakrzewski on an April 18, 2011 conference call, regarding the phase III trial results of the ANCHOR study:

> "[f]or ANCHOR, we have that substantially underway as we talked about. The FDA has signaled to us that, is that 25% of the patients, is that 50% of the patients enrolled. What I was trying to signal on the past discussions, or on the past calls are, because of the data we're seeing and because of the dialogues that we're having with the agency, there are possibilities that it could be negotiated differently. . . . If you take it at its face value, it's probably a quarter to half the patients prior to a formal submission."

SAC ¶ 262. According to Plaintiff, Zakrzewski's claim that 25% to 50% of patients needed to be enrolled in REDUCE-IT to apply for the ANCHOR indication was materially and knowingly false, because "the July 6, 2009 SPA [and the 2008 Minutes] clearly stated that 50% of patients needed to be enrolled in REDUCE-IT before the FDA would accept the ANCHOR sNDA for filing." SAC ¶ 263.

However, Plaintiff fundamentally mischaracterizes the language of the 2008 Minutes and the 2009 SPA. The 2008 Minutes do not include a specific required percentage enrollment, but

rather state that that the REDUCE-IT study must be "well underway" and have "approximately half of the patients enrolled" before Amarin may apply for the ANCHOR indication. *See* Wuertz Decl. Ex. A at 10. Likewise, the 2009 SPA is completely silent as to the specifics of this requirement.[10] *See* Wuertz Decl. Ex. C. *See* SAC ¶ 278. Indeed, Defendants claim that the definitive 50% requirement was not finalized until the 2011 SPA was executed on August 5, 2011 — almost four months after Zakrzewski's allegedly misleading statement was made. Mem. of Law in Supp. of Defs.' Mot. to Dismiss. ("Defs.' Supp. Br.") 16. Defendants argue that because at the time Zakrzewski spoke, the FDA had not yet finalized the percentage enrollment that would be necessary for the REDUCE-IT study to be "well underway," Zakrzewski's approximated range of 25% to 50% was not a mischaracterization of the FDA's position at the time. *Id.*

Curiously, Defendants cite to Amarin's August 10, 2011 Form 8-K in support of this assertion, rather than the text of the 2011 SPA. *Id.* at 16. The Form 8-K contains a press release entitled "Amarin Announces Agreement from FDA on Special Protocol Assessment for AMR101 Outcomes Study," which states in pertinent part that "[t]he Company anticipates that if, as intended, it commences Outcomes study activities in 2011 that it will be positional to achieve

[10] Plaintiff counters in his briefings that according to a letter drafted by Ketchum on February 27, 2014, Ketchum admitted that "[a]n essential component of the [2009 SPA] Agreement is the requirement that approximately 50% of patients be enrolled in [REDUCE-IT] before the Division would accept submission [of] the sNDA." However, setting aside the fact that Plaintiff may not amend his Complaint through his briefings, *see Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.), the 2008 Minutes and 2009 SPA speak for themselves. The fact that Plaintiff cannot point to any part of these documents to support his assertion, and instead relies on an after-the-fact characterization of the document, belies the truth that he alleges insufficient facts to show that Zakrzewski's statement was materially false or misleading at the time it was made.

approximately 50% enrollment before the end of 2012."[11] Wuertz Decl. Ex. W at 6. Although I am hesitant to rely on a document describing the 2011 SPA, rather than the agreement itself, Defendants' claims regarding the content of the 2011 SPA are also supported by Plaintiff's allegation that in the 2011 SPA "Amarin sought the FDA's agreement, that the 'design and size' of the CVOT REDUCE-IT study, 'prior to completion, will support the indication (to be applied for with adequate results from [the ANCHOR] study . . . and approximately 50% enrollment in REDUCE-IT.'" SAC ¶ 32; *see also* SAC ¶ *278*. Furthermore, Defendants' asserted timeline is also consistent with other of Amarin's SEC filings from the period prior to Zakrzewski's statement, which state that the REDUCE-IT study must be "substantially underway," and do not mention a specific percentage enrollment. *See* Wuertz Decl. Exs. E at 5 (Amarin's Form 10-K filed March 16, 2011, which states that "in order to seek approval for a potentially expanded indication, we will be required to have substantially enrolled subjects in a medical 'outcomes study' at the time of our NDA submission."), H. at 71 (Amarin's Form 8-K dated April 18, 2011, which states that "[i]n order to obtain a separate indication for AMR101 based on the ANCHOR trial results, the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA filing.").

Taking into account the allegations and documentary evidence as a whole, the Court disagrees with Plaintiff that 25% to 50% enrollment is a misrepresentation of the FDA's requirement in the 2008 Minutes that the study be "well underway" with "approximately half of the patients enrolled." Zakrzewski's percentage range of 25% to 50% falls within the bounds of "approximately half." Therefore, considering the actual language of the 2008 Minutes and the

[11] As matters of public record, I may consider Amarin's filings with the SEC on this motion to dismiss. *In re Rockefeller*, 184 F.3d at 292.

2009 SPA, Zakrzewski's statement is not a mischaracterization of the FDA's position as of the date the statement was made. *See In re NAHC,* 306 F.3d at 1330 (A statement or omission must have been materially misleading at the time it was made.).

Furthermore, the Court does not find that Zakrzewski's alleged misrepresentation is material. It seems unlikely that a reasonable shareholder would change her investment choices, if Amarin was only required to enroll 25%, rather than 50%, of the patients in the REDUCE-IT study prior to application for the ANCHOR indication. *See Basic*, 485 U.S. at 231-32 (A misrepresentation or omission of fact is material "if there is a substantial likelihood that a reasonable shareholder would consider it important" in making an investment decision.). Under the facts alleged, the crux of this litigation, and the information that reasonable investors would have considered important, was whether REDUCE-IT needed to be *completed* before the application for the ANCHOR indication could be filed. Given that Amarin had already announced that the study needed to be substantially underway to apply for the ANCHOR indication, the question of how many patients needed to be enrolled in the study for it to be considered "substantially underway" would not be significant. Moreover, Plaintiff does not allege that the price of Amarin's stock was affected by either Zakrzewski's statement or the ultimate revelation of the "true facts" regarding the required enrollment. Accordingly, the Court finds that considering these facts as a whole, there is not a substantial likelihood that a reasonable shareholder would consider Zakrzewski's statement important or that a disclosure of the exact wording used by the FDA in the 2008 Minutes "would have been viewed by a reasonable investor as having significantly altered the 'total mix' of information made available." *See Id.* Thus, Plaintiff has failed to allege facts under which Zakrzewski's statement is materially false or misleading. Accordingly, this statement cannot form the basis of a Rule 10b-5 action.

iii. Statements Regarding the JELIS Trial

In the SAC, Plaintiff re-alleges that prior to and throughout the Class Period, Defendants falsely and misleadingly "cited the JELIS study as support for the efficacy of Vascepa for the ANCHOR indication," despite the fact that JELIS "was not sufficiently comparable to the ANCHOR trial to warrant Defendants' comparisons." SAC ¶¶ 169, 171. This same claim was previously dismissed in the June 26, 2015 Opinion, because the Court found that the two such statements, cited by Defendants in the CAC, "were not materially false or misleading" and did not actually compare the JELIS trial to the ANCHOR trial. *In re Amarin*, 2015 U.S. Dist. LEXIS 84080, at *47-50. In the SAC, Plaintiff attempts to buttress this claim with new allegations that during the 2008 Meeting, the FDA advised Amarin that JELIS did not support the ANCHOR indication for Vascepa, additional allegations of materially false statements concerning JELIS, and allegations that Amarin corrected its materially false and misleading statements with regards to JELIS in its 2013 Form 10-K. *See* SAC ¶¶ 172-74, 180, 292, 361, 381. However, for the reasons set forth below, the Court again finds that Defendants' statements regarding the JELIS study were not materially false or misleading.

The JELIS study was the first large-scale, prospective, randomized trial of combined treatment with a statin and an omega-3 fatty acid originally derived from fish, i.e. EPA. SAC ¶ 167. The study tested the effects of long-term use of EPA, in combination with a statin, on Japanese patients with hypercholesterolemia. SAC ¶ 167. Ultimately, the study demonstrated that "the addition of EPA to statin therapy provides additional benefit in preventing major coronary events, apparently through lipid-independent mechanisms." SAC ¶ 168. Although the FDA viewed the

JELIS results as "encouraging,"[12] Wuertz Reply Decl. Ex. FF at 6, nonetheless, the FDA warned Amarin at the 2008 Meeting that it could not rely on the results of the JELIS study in lieu of conducting its own outcomes study, due to differences in design, protocol, and patient populations. SAC ¶¶ 172-76; Wuertz Decl. Ex. A. Plaintiff identifies the differences between the JELIS trial and the ANCHOR trial as follows: (1) "the ANCHOR trial was double-blind (neither participants nor researchers were aware of which treatment each participant was receiving)," SAC ¶ 171; (2) "whereas over 90% of the patients in the ANCHOR trial were on medium to high doses of statins, by design, all of the patients in the JELIS study were on low doses of statin," SAC ¶ 176, and (3) "the study was conducted in a Japanese population which is very different [from an American population] in terms of fish intake and cardiac event rate." SAC ¶ 22.

Plaintiff alleges, that based on the FDA's warning, "Defendants had actual knowledge of critical distinctions between JELIS and ANCHOR and REDUCE-IT and knew that the JELIS study was not indicative of efficacy of Vascepa for the ANCHOR indication." SAC ¶ 172. Thus, Plaintiff asserts that "[w]hen Defendants chose to speak about JELIS, they had an obligation to disclose the whole truth, including the FDA's position that JELIS was not indicative of efficacy of Vascepa for the ANCHOR indication." SAC ¶ 177. Plaintiff cites to five allegedly materially false and misleading statements by Defendants, in which Defendants claimed that "the JELIS study

[12] In minutes from a December 16, 2013 meeting between Amarin and the FDA, the FDA stated that "Regarding the JELIS trial . . . the results are encouraging and we hope that REDUCE-IT will produce similar results. JELIS does, however, have limitations . . . ." Wuertz Reply Decl. Ex. FF at 6. The Court may properly consider the December 16, 2013 meeting minutes on this motion to dismiss, because this document is explicitly relied upon in the pleadings. *See Burlington*, 114 F.3d at 1426.

was indicative of the efficacy of Vascepa for the ANCHOR indication," but failed to disclose the FDA's position on JELIS.[13] SAC ¶ 212.

[13] The five alleged statements at issue are as follows:

(1) "On a September 25, 2008 conference call, approximately 40 days after Amarin's July 14, 2008 meeting with the FDA, Amarin's then Chairman and Chief Executive Officer, mischaracterized Amarin's Vascepa development program as 'a near-term, low-risk, high-value development opportunity whose safety has been established and efficacy of EPA-based products proven in multiple studies around the world.'" SAC ¶ 184.

(2) "The [2010] 10-K (at page 6) also discussed JELIS as establishing a successful outcomes study for the ANCHOR indication of Vascepa:

> Among the reasons why Phase II trials were not conducted or required is that the active ingredient in Vascepa, ethyl-EPA of not less than 96% purity with no DHA, has been approved by regulatory authorities in Japan and marketed by Mochida Pharmaceutical Co. for over a decade. In Japan, ethyl-EPA is marketed under the product name of Epadel and is indicated for hyperlipidemia and peripheral vascular disease and which we understand has 2009 revenues in Japan that exceed $500 million per year. Clinical data from Japan shows that Epadel is effective in reducing TGs. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study or JELIS Study (JELIS), which study consisted of more than 18,000 patients followed over multiple years, Epadel, when used in conjunction with statins, was shown to reduce cardiovascular events by 19% compared to the use of statins alone. In this study, cardiovascular events decreased by approximately 53% compared to statins alone in the subset of patients with triglyceride levels of 150 mg/dL (average 269 mg/dL at entry) and HDL-C <40 mg/dL." SAC ¶ 236.

(3) "The August 10[, 2011] press release quoted defendant Zakrzewski as making the further materially false and misleading statement:

> 'Based on the strong safety profile of [Vascepa], our positive Phase 3 results for [Vascepa] and success in Japan with an outcomes study of highly pure EPA, we believe that REDUCE-IT is positioned for success.'" SAC ¶ 292.

(4) On a May 9, 2013 conference call, "Zakrzewski concluded his remarks on the call by saying, with respect to JELIS, that:

> [A]t the end of the day for us it's about JELIS. That's the best comparator for our study, for our drug. And you know, JELIS is a study that in Japan saw a 19% reduction in mortality with our sister drug Epadel. And when they looked at patients at higher trig levels, they saw a 53% [reduction]. That's the one we should be thinking about, not supplements, not poorly designed old studies." SAC ¶ 361.

(5) Defendant Ketchum made the following statement on an August 8, 2013 conference call:

> "While we believe we do not need the REDUCE-IT study to be completed for approval of the ANCHOR indication, we do believe that this study is positioned for success. Highly

The Court, however, does not find these statements to be either materially false or misleading. Plaintiff does not allege facts demonstrating that the JELIS study was not, at least in some manner, indicative of the efficacy of Vascepa for the ANCHOR indication. And indeed, the FDA's description of the JELIS study results as "encouraging," demonstrates that, to some extent, the FDA considered JELIS indicative that Vascepa might eventually prove effective for the ANCHOR indication. *See* Wuertz Reply Decl. Ex. FF at 6. Furthermore, although in the 2008 Minutes the FDA warns that JELIS would be insufficient to form the basis for approval of Vascepa for the ANCHOR indication, it does not expressly deny that the success of JELIS has positive implications for the possible success of Vascepa. Wuertz Decl. Ex. A at 10. Importantly, Plaintiff does not allege that Defendants ever represented to investors that the FDA would approve Vascepa based solely on JELIS. Instead, under the facts alleged, Defendants' statements merely express optimism that the JELIS results would ultimately be replicated in Amarin's own outcomes study, REDUCE-IT. *See* SAC ¶¶ 292, 361, 381.

Plaintiff also argues that when Amarin acknowledged in its 2013 Form 10-K (filed with the SEC on February 27, 2014) that there were "several limitations to the JELIS study" it essentially admitted that its prior optimistic statements were materially false or misleading. *See*

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pure EPA in the JELIS study, albeit in a Japanese population demonstrated significant reduction in cardiovascular events over statin therapy alone. . . .

It is unfortunate that the authors of that med analysis did not identify that the one study which was successful with the JELIS study of our sister drug Epadel in which highly pure EPA was affected in improving cardiac outcomes on top of statin therapy in Japanese patient population.

Overall, we have seen nothing presented anywhere that has diminished our overall confidence in the clinical opportunity provided by Vascepa. Our advisors and thought leaders agree, and urge that we be focused on more relevant topics such as reduced LDL particle concentration from Vascepa, the anti-inflammatory response of Vascepa and incremental efficacy of Vascepa on top of increased potency of statin therapy." SAC ¶ 381.

SAC ¶ 180. However, an examination of the document itself reveals that Amarin's 2013 Form 10-K is consistent with Defendants' other alleged statements regarding JELIS. *See* Wuertz Decl. Ex. B at 35. In addition to acknowledging the limitations of the JELIS study, like Defendants' other statements, the 2013 Form 10-K also cites to the JELIS study as evidence that EPA has previously been found to be effective in treating MACE, when used in conjunction with statins. *Id.*

In sum, Plaintiff has failed to sufficiently allege that the JELIS study was not indicative, at least in some manner, of the potential efficacy of Vascepa for the ANCHOR indication. Accordingly, as a matter of law, Defendants' statements regarding the positive implications of the JELIS study results were not materially false or misleading and cannot form the basis of a Rule 10b-5 action.

iv. Statements Regarding the Importance of the ACCORD and AIM-HIGH Studies

In the CAC, Plaintiff previously alleged that Defendants misrepresented that the long-term REDUCE-IT study was not required to be completed for FDA approval of the ANCHOR indication, when Defendants knew that such a study was likely to be required. *See* CAC ¶¶ 127; 158; 163; 164; 168-69; 174; 187; 213; 261; 281-84. According to Plaintiff, Defendants knew the completion of the REDUCE-IT study was likely to be required, because the FDA indicated that the outcomes of the long-term ACCORD and AIM-HIGH trials would provide "important information," and when both trials were ultimately unsuccessful, it became "substantially less likely" that the FDA would approve the ANCHOR indication without the completion of the REDUCE-IT study. CAC ¶¶ 93, 119. In the June 26, 2015 Opinion, the Court rejected this theory, because, among other things, Plaintiff had not alleged that Defendant made statements

affirmatively characterizing the importance of the ACCORD and AIM-HIGH studies. *In re Amarin*, 2015 U.S. Dist. LEXIS 84080, at *33. Instead, the Court found that "Defendants are merely alleged to have stated, correctly, that the studies were not required to be completed in order for the ANCHOR indication application process to continue." *Id*.

In the SAC, Plaintiff attempts to remedy this deficiency by newly alleging that on five occasions, prior to and during the Class Period, Defendants made statements mischaracterizing the importance of the ACCORD or AIM-HIGH studies.[14] *See* SAC ¶¶ 124-25. In two of the

[14] The five alleged statements at issue are as follows:

(1) "At a Thomson Reuters Future Leaders in the Biotech Industry Conference, on April 8, 2010, Declan Doogan, as Interim Chief Executive Officer, stated, on behalf of Amarin, that whereas the ACCORD study had been a failure and demonstrated the disutility of fibrates in treating cardiovascular disease, JELIS had been a success and demonstrated the utility of ethyl-EPA, the active ingredient in Vascepa, in treating CV disease." SAC ¶ 124(a).

(2) "In a presentation on May 3, 2010 at the Deutsche Bank Securities Health Care Conference, defendant Thero stated that fibrates had been dealt a setback in treating triglycerides by virtue of the ACCORD study." SAC ¶ 124(b).

(3) "Declan Doogan, in a presentation to the Rodman & Renshaw Global Investment Conference, on May 19, 2010, as Chief Executive Officer of Amarin, again contrasted the success of the JELIS study to the failure of ACCORD ("which failed to show significant benefit in cardiovascular risk modification")." SAC ¶ 124(c).

(4) "Defendant Zakrzewski, on an April 18, 2011 Amarin conference call, stated that the ACCORD failure provided a competitive benefit for Vascepa ("[I]n the ACCORD studies and others, Trilipix and others didn't perform very well, particularly in high statin does. And so we think that's another real benefit for us.")." SAC ¶ 124(d).

(5) "Defendant Ketchum presented on an August 8, 2013 conference call that the failure of ACCORD and AIM-High would not have implications on approval [sic] of Vascepa." SAC ¶ 124(e). Specifically, Ketchum stated:

"Some investors have argued that because the AIM-HIGH study with Niacin failed, that the FDA will change its view on Vascepa. As a reminder, Niacin is an HPO raising drug not a triglyceride lowering drug and Niacin remains approved on the market. Some also argue the Fenofibrate [sic] failed the outcomes studies and this will have a bearing on getting the FDA to reassess its requirement for Vascepa. Fenofibrate were not directly studied in a patient population with alleviated triglycerides in an outcomes setting. In fact,

statements, Doogan, Amarin's interim chief executive officer, noted that the ACCORD study (of fibrates) had "been a failure" while the JELIS study (of EPA) had been a success. SAC ¶ 124(a), (c). In two more of the statements, Thero and Zakrzewski each expressed the view that fibrates "didn't perform very well" in the ACCORD trial, and had been "dealt a setback" by the study's results. SAC ¶ 124 (b), (d). Finally, in the fifth statement, Ketchum allegedly claimed that "the failure of ACCORD and AIM-HIGH would not have implications on approval [sic] of Vascepa." SAC ¶ 124 (e).

According to Plaintiff, "At no time did defendants disclose the truth that the FDA had informed Amarin in July 2008 that the AIM-HIGH and ACCORD trials 'will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy,' and therefore that the failure of the AIM-HIGH and ACCORD studies would bear on the willingness of the FDA to approve ANCHOR based only on a twelve-week study of surrogate endpoints." SAC ¶ 125. Notably, Plaintiff did not explicitly explain in the SAC, why each of these five statements was misleading such that a disclosure of this kind was necessary. *See Winer Family Trust*, 503 F.3d at 326 (To state a claim for securities fraud, a plaintiff must "specify each allegedly

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in the ACCORD study of fenofibrates, the subgroup of patients who had alleviated baseline triglycerides showed improved outcomes.

This has not been widely publicized because this was not the pre-specified primary endpoint of the study and the study was not powered for this purpose, but it is supportive of the value of lowering triglyceride levels in patients with high triglycerides. In addition, Vascepa not only lowers triglycerides but lowers distraction of other lipid parameters including, compared to placebo, LDL-C, a well established marker of outcomes and Vascepa also lowered various other inflammatory biomarkers. Vascepa does this with a safety profile which is comparable to placebo.

Today, patients with alleviated triglycerides are being treated on-label or off-label with a variety of drugs which increase LDL or have various other side effects. We find it difficult to believe that given this environment and the safety and efficacy profile of Vascepa, that Vascepa won't be approved for this expanded indication." SAC ¶ 381.

misleading statement" and "why the statement was misleading."). And indeed, the Court is at a loss as to how, under the facts alleged, the first four of the five statements could be considered materially false or misleading.

To that point, Doogan's two statements accurately observed that the failure of the ACCORD study had been a blow for fibrates, while the success of the JELIS study was evidence of the utility of EPA. SAC ¶ 124(a), (c). Plaintiff alleges no facts demonstrating that these observations are untrue. Presumably, Plaintiff is attempting to argue that by emphasizing the potential upside of the failure of the ACCORD study — a setback for a competitor drug (fibrates) — Doogan misleading implied that the ACCORD study has absolutely no downside for Amarin, when he actually knew that it "would bear on the willingness of the FDA to approve ANCHOR based only on a twelve-week study of surrogate endpoints." SAC ¶ 125. However, the Court does not read Doogan's statements in this manner. Taking Doogan's statements in the context of all facts alleged, his remarks regarding the potential benefits of the ACCORD study would not have lead a reasonable investor to believe that there were no corresponding potential negatives. Moreover, because Doogan's statements are his opinions on the implications of the ACCORD and JELIS studies, to state a claim, Plaintiff would have to allege facts showing that either (1) Doogan did not honestly believe these opinions, or (2) the opinions had no reasonable basis. *See City of Edinburgh*, 754 F.3d at 170 (3d Cir. 2014) ("[o]pinions are only actionable under securities laws[, including Section 10(b),] if they are not honestly believed and lack a reasonable basis."). Plaintiff has failed to plead such facts. Thus, because Plaintiff does not sufficiently allege that these statements were misleading, Doogan had no duty to disclose the FDA's admonition at the 2008 Meeting that the ACCORD study would provide "important information." *See Matrixx*, 563 U.S.

at 44 ("Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'").

Similarly, the allegedly false or misleading statements by Thero and Zakrzewski were neither materially false nor misleading. Plaintiff does not allege facts indicating that the failure of the ACCORD study would not provide a benefit to Amarin, by thinning the field of competition. And, like Doogan's statements, Thero and Zakrzewski's statements do not preclude the possibility that the ACCORD study might also somehow harm Amarin. Finally, Plaintiff does not allege that Thero and Zakrzewski did not honestly believe these statements or that the statements had no reasonable basis. Therefore, as with Doogan, Plaintiff does not allege facts under which Thero and Zakrzewski would have had a duty to disclose the FDA's posture at the 2008 Meeting.

As to the fifth allegedly false statement, on its face, Ketchum's claim "that the failure of ACCORD and AIM-HIGH would not have implications on approval [sic] of Vascepa," SAC ¶ 124(e), seems to directly contradict the FDA's statement at the 2008 Meeting that the ACCORD and AIM-HIGH studies "will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy," SAC ¶ 20. However, inspection of the transcript of Ketchum's statement, reveals that he did not actually claim that ACCORD and AIM-HIGH were irrelevant, or would not have implications for Vascepa. SAC ¶ 381. Instead, Ketchum observed that "[s]ome investors have argued that because the AIM-HIGH study with Niacin failed, that the FDA will change its view on Vascepa," and contrasted that view with the fact that Niacin could be distinguished from Vascepa in certain ways — "Niacin is an HPO raising drug not a triglyceride lowering drug ." SAC ¶ 381. In that connection, Ketchum also noted that despite the failure of the AIM-HIGH study, "Niacin remains approved on the market." SAC ¶ 381. Additionally, Ketchum noted that "[s]ome [investors] also argue the Fenofibrate [sic] failed the outcomes studies and this

will have a bearing on getting the FDA to reassess its requirement for Vascepa," but then gave counter-arguments as to why that might not come to pass. SAC ¶ 381. Specifically, Ketchum pointed to the fact that "[f]enofibrate[s] were not directly studied in a patient population with alleviated triglycerides in an outcomes setting" and the fact that those patients in the ACCORD study who did have alleviated triglycerides showed improved outcomes. SAC ¶ 381.

Essentially, in his statement, Ketchum acknowledged investor concerns that the AIM-HIGH and ACCORD studies might prevent FDA approval of Vascepa for the ANCHOR indication, and gave reasonable arguments as to why this was not likely to be the case. SAC ¶ 381. He did not, as Plaintiff alleges, claim that these studies would not have any implications for the approval of Vascepa.

Plaintiff argues that Ketchum's statement was "materially false and misleading because it conflicts with the FDA's advice to Amarin that the ACCORD and AIM-HIGH studies 'will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy.'" Pl.'s Opp'n Br. at 12. However, Ketchum's statement does not deny that the FDA ever gave Amarin such advice, and therefore, is not an outright misrepresentation. Moreover, it strains the bounds of credulity to argue that a reasonable investor would be misled by Ketchum's statement, when he expressly acknowledged that others disagreed with him on these points. But, even assuming that Ketchum's statement was somehow misleading, it is an inactionable statement of opinion, because Plaintiff does not allege that it was not honestly believed or lacked a reasonable basis. *City of Edinburgh*, 754 F.3d at 170. Indeed, Plaintiff does not allege facts demonstrating that Ketchum's counter-arguments distinguishing the ACCORD and AIM-HIGH studies are objectively unreasonable or are not based in actual fact. Moreover, Plaintiff does not allege that Ketchum did not honestly believe these arguments. The fact that Ketchum was ultimately wrong

in his beliefs is not a basis, by itself, to bring a claim under Section 10(b). *See In re NAHC*, 306 F.3d at 1330.

In sum, the Court finds that Plaintiff has failed to sufficiently allege that the five statements regarding the importance of the ACCORD and AIM-HIGH studies were materially false or misleading. Therefore, these statements do not support Plaintiff's Section 10(b) claim.

v. Statements Regarding the Use of TG Levels as a Surrogate Endpoint

Plaintiff alleges that in correspondence submitted in the NY Action, Ketchum acknowledged that "the July 2009 SPA reflected that the FDA 'recognized substantial uncertainties around the connection between the potential effects of Vascepa . . . in the ANCHOR population and cardiovascular risk reduction.'" SAC ¶ 10(c). However, according to Plaintiff, in spite of Defendants' knowledge of the FDA's "substantial uncertainties," they made false and misleading "[s]tatements that Amarin had reached an agreement with the FDA on the analysis of the ANCHOR study" and "that the FDA was receptive to TG lowering as a surrogate endpoint." SAC ¶ 209(iii). Additionally, Plaintiff alleges that Defendants falsely and misleading stated that the "reduction of TGs was an accepted surrogate for the reduction of CVD." SAC ¶ 209(iv). Plaintiff cites to twenty-seven allegedly materially false or misleading statements made by Defendants to this effect.[15] SAC ¶¶ 185, 187, 189, 191, 192, 193, 194, 240, 241, 258, 261, 270, 284, 287, 298, 311, 313, 322, 323, 324, 325, 331, 336, 358, 359, 379, 381.

[15] The twenty-seven statements at issue were made on the following occasions:

(1) a September 24, 2008 conference call, SAC ¶ 185; (2) a July 9, 2009 press release, SAC ¶¶ 187, 189, 191, 192, 193, 194; (3) a March 17, 2011 conference call, SAC ¶¶ 240, 241; (4) an April 18, 2011 conference call, SAC ¶¶ 258, 261, 261; (5) a May 10, 2011 conference call, SAC ¶ 270; (6) an August 9, 2011 press release, SAC ¶ 284; (7) an August 10, 2011 earnings call, SAC ¶ 287; (8) a January 3, 2012 letter to shareholders, SAC ¶ 298; (9) a May 8, 2012 press release, SAC ¶ 311; (10) a May 8, 2012 conference call, SAC ¶ 313; (11) a July 26, 2012 conference call, SAC ¶¶ 322, 323, 324, 325; (12) an August 8, 2012 press release, SAC ¶ 331; (13) an August 8, 2012 earnings

However, Plaintiff has failed to plead facts rendering these statements materially false or misleading. Under the facts alleged, it is clear that at the time the 2009 SPA and 2011 SPA were executed, the reduction of TGs was still an accepted surrogate for the reduction of MACE. *See* SAC ¶¶ 32, 126-27, 137, 141. According to a letter from Dr. John Jenkins, the Director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research, which Plaintiff cites in the SAC: "at the time of the pre-IND meeting on July 18, 2008, (as well as at the time of the ANCHOR SPA agreement) DMEP [the FDA's Division of Metabolism and Endocrinology Products] was still willing to accept TG lowering as a validated surrogate for reducing CV risk." SAC ¶ 137. To that point, the 2009 SPA originally specified that Amarin could apply for the ANCHOR indication based only on the results of the ANCHOR study, which utilized lowering TG levels as a surrogate endpoint for lower MACE. SAC ¶¶ 126-27. Importantly, both the 2009 SPA and the 2011 SPA did not mandate the completion of a MACE outcomes study (REDUCE-IT) as a prerequisite for application for the ANCHOR indication. SAC ¶¶ 32, 126-27. This demonstrates that prior to and during the period in which these SPAs were signed, the FDA accepted the use of TG levels as a surrogate endpoint for MACE outcomes.

Furthermore, this fact is also clear from the language the FDA used when it ultimately rejected Amarin's ANCHOR application. *See* SAC ¶ 141. In its Special Protocol Assessment – Rescind Agreement, dated October 29, 2013, the FDA stated that it had rejected the application because "a substantial scientific issue essential to determining the effectiveness of Vascepa in this [high TG] population was identified *after testing began*." SAC ¶ 141 (emphasis added). This emergent substantial scientific issue was that "the results from the ACCORD-Lipid and AIM-

call, SAC ¶ 336; (14) a May 9, 2013 press release, SAC ¶ 358, (15) a May 9, 2013 conference call, SAC ¶ 359; and (16) an August 8, 2013 press release, SAC ¶¶ 379, 381.

HIGH trials, as well as the publicly presented results from the HPS2-THRIVE trial, fail[ed] to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among statin-treated patients."[16] Reply Decl. of Allison M. Wuertz in Further Supp. of Defs.' Mot. to Dismiss the SAC ("Wuertz Reply Decl.") Ex. CC at 1. Because, according to the FDA, the TGs-as-surrogate hypothesis was only undermined after the ANCHOR study was already underway, it must have been accepted prior to that discovery. Thus, contrary to Plaintiff's assertions, it is clear that when the 2009 SPA and 2011 SPA were executed, TG levels were an accepted surrogate for the reduction of MACE.

Presumably, Plaintiff would argue that although TG levels were previously an accepted surrogate, at the time Defendants made statements to this effect, this was no longer the case. However, Plaintiff alleges no facts indicating that during this period the FDA expressly communicated to Defendants that it would no longer accept TG levels as a surrogate. Instead, under the facts alleged, the FDA did not officially reverse its policy towards the TGs-as-surrogate hypothesis until October 2013, when it considered and rejected Amarin's application for the ANCHOR indication. None of the statements at issue were made after October 2013. *See* SAC ¶¶ 185, 187, 189, 191, 192, 193, 194, 240, 241, 258, 261, 270, 284, 287, 298, 311, 313, 322, 323, 324, 325, 331, 336, 358, 359, 379, 381. Therefore, Plaintiff has failed to allege that Defendants' statements "that Amarin had reached an agreement with the FDA on the analysis of the ANCHOR study, that the FDA was receptive to TG lowering as a surrogate endpoint," and that the "reduction of TGs was an accepted surrogate for the reduction of CVD" were either materially false or

[16] The Court may properly consider the Special Protocol Assessment – Rescind Agreement on this motion to dismiss, because this document is explicitly relied upon in the pleadings. *See Burlington*, 114 F.3d at 1426.

misleading. *See* SAC ¶¶ 209(iii), 209(iv). Accordingly, these statements cannot form the basis of Plaintiff's Section 10(b) claim.

vi. Statements Regarding the Mineral Oil Placebo in the ANCHOR Study

In the CAC, Plaintiff alleged that "Defendants suppressed concerns regarding the use of mineral oil as the placebo in the ANCHOR study." *See* CAC ¶¶ 72-85; 143; 249. Specifically, Plaintiff alleged that Defendants stated, on numerous occasions, that "(i) the use of mineral oil as a placebo did not raise any specific concerns with respect to the anticipated approval of the ANCHOR sNDA [supplemental new drug application] by late 2013, (ii) that the ANCHOR study achieved its primary and secondary endpoints, and (iii) that Amarin anticipated approval of the ANCHOR sNDA without completing an outcomes study," all of which was materially false and misleading, because "[a]ccording to the FDA's statements at the [October 16, 2013] Advisory Committee Meeting, the FDA's [concerns] with the use of mineral oil as placebo was [sic] shared with Amarin prior to the AdCom." CAC ¶ 143(iii).

In the June 26, 2015 Opinion, I dismissed these claims, finding that for multiple reasons, Defendants' alleged statements were neither materially false nor misleading. *In re Amarin*, 2015 U.S. Dist. LEXIS 84080, at *35-45. First, I observed that Plaintiff had not alleged that any FDA concerns about the mineral oil placebo were so serious as to place the ANCHOR study, and thus FDA approval of the ANCHOR indication, in jeopardy. *Id.* Moreover, I noted that under the alleged facts, the FDA had approved the use of mineral oil as a placebo in its SPA with Amarin.[17] *Id.* Second, I found that Plaintiff had failed to plead when the FDA expressed its concerns to Amarin about the mineral oil placebo. *Id.* at *45. Therefore, I reasoned, that even if I were to

[17] Indeed, the 2008 Minutes appear to indicate that any FDA concerns expressed at that time regarding the mineral oil placebo were resolved at the meeting. *See* Wuertz Decl. Ex. A at 8.

conclude that positive statements about the study in the wake of such concerns were materially false or misleading, I would be unable to determine which statements were made after the concerns were expressed. *Id*.

In the SAC, Plaintiff re-pleads claims, nearly identical to those previously dismissed by the Court, based on Defendants' statements regarding the use of mineral oil as a placebo in the ANCHOR study. Plaintiff only makes two new allegations in support of these claims: (1) that the discussions in which the FDA expressed its concerns to Amarin that the mineral oil placebo was not inert, "likely took place between April 18, 2011 and August 5, 2011, subsequent to the release of the ANCHOR study and prior to the August 5, 2011 REDUCE-IT SPA," SAC ¶ 104, and (2) that "[t]he FDA had informed Amarin at the July 2008 meeting that test results would have to be 'robust' to justify consideration for approval based on one study of surrogate endpoints," SAC ¶ 105. These new allegations do not provide a sufficient basis for Plaintiff to allege that Defendants' statements regarding the use of mineral oil as a placebo were materially false or misleading. And indeed, in his brief, Plaintiff even concedes that "these allegations are not likely to be sufficient for this Court to reconsider its Opinion with respect to mineral oil." Pl.'s Opp'n Br. at 4 n 5.

First, I note that alleging that discussions "likely" took place between two dates is insufficient to satisfy the heightened pleading standard of Rule 9(b) and the PSLRA. *See Avaya*, 564 F.3d at 253 (Rule 9(b)'s particularity requirement "is comparable to and effectively subsumed by the requirements of [§ 78u-4(b)(1) of] the PSLRA."); *In re Suprema*, 438 F.3d at 276-77 (Rule 9(b) requires a plaintiff to allege the "essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue."). Furthermore, if Plaintiff was to allege these dates on information and belief, he would

also need to allege "all facts supporting that belief with particularity." *Winer Family Trust*, 503 F.3d at 326 (construing 15 U.S.C. § 78u-4(b)(1)). Plaintiff has not satisfied this pleading requirement.

Additionally, Plaintiff's new allegations do not cure the primary deficiency in his claim — namely that he does not allege that the FDA's concerns about the mineral oil placebo were so serious as to place the ANCHOR study and, thus, FDA approval of the ANCHOR indication, in jeopardy. *See In re Sanofi Secs. Litig.*, 87 F. Supp. 3d 510, 533 (S.D.N.Y. 2015) (finding that defendants' omissions regarding FDA concerns about a clinical trial to not be materially false or misleading statement because "[d]espite the concerns the FDA had expressed about the design of the clinical trials, it allowed those trials to proceed."); *cf. In re MedImmune*, 873 F. Supp. at 966 ("Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process . . . . Requiring ongoing disclosure of FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than not reporting the questions."). Plaintiff argues that "the added uncertainty caused by the use of mineral oil, and the adverse test results experienced by patients while on placebo," caused the test results to be "anything but 'robust,'" and thereby put the ANCHOR study in jeopardy. SAC ¶ 105. However, this argument is tenuous at best, and, as pointed out in the Court's previous Opinion, is directly contradicted by the fact that the FDA approved the use of mineral oil as a placebo in the 2009 SPA.

Accordingly, the Court finds that Plaintiff has again failed to plead that Defendants' statements regarding the use of mineral oil as a placebo in the ANCHOR study are materially false or misleading so as to sustain a Rule 10b-5 action.

vii. Claims that Positive ANCHOR Results Will Stimulate Additional Interest from Commercial Partners

Plaintiff alleges that both Amarin and Thero made materially false and misleading statements claiming that "the positive ANCHOR results 'will stimulate additional interest from commercial partners.'" SAC ¶ 209(vii). Plaintiff claims that these statements were materially false and misleading because "[t]hose 'commercial partners' would certainly have reviewed the regulatory record prior to committing resources to Amarin, and having done so, would recognize that approval of the ANCHOR indication would require the completion of the REDUCE-IT study, and would [therefore] be dissuaded from investing in Amarin." SAC ¶ 209(vii). Plaintiff cites to two allegedly materially false and misleading statements to this effect: one made by Amarin, in its January 6, 2011 Prospectus Supplement on Form 424B5, and the other made by Thero, on an April 18, 2011 conference call.[18] SAC ¶¶ 229, 260.

At the outset, I note that Plaintiff completely mischaracterizes the nature of Amarin's alleged statement. Amarin does not, as Plaintiff asserts, claim that positive ANCHOR results will stimulate additional interest from commercial partners. Rather, Amarin merely notes that if it elects

[18] (1) Amarin allegedly stated that "[i]n order to obtain a separate indication for Vascepa based on the ANCHOR trial results, the Food and Drug Administration, or FDA, requires that we have a clinical "outcomes study" substantially underway at the time of filing a New Drug Application, or NDA. If we elect to seek this separate indication in our initial NDA filing and commence an outcomes study, we will need to seek additional financing, through a commercial partner or otherwise. The results of an outcomes study are not required for FDA approval of the broader indication, and an outcomes study is not required for the indication being studied in the MARINE trial." SAC ¶ 229.

(2) Thero allegedly stated that "[w]e anticipate that the positive ANCHOR results will stimulate additional interest from potential commercial partners. [G]iven the strongly positive nature of the ANCHOR results, we anticipate that the pace of such discussions may accelerate, and together with our advisors, we are taking steps to accelerate such discussions." SAC ¶ 260.

to seek the ANCHOR indication for Vascepa, it "will need to seek additional financing, through a commercial partner or otherwise." SAC ¶ 229. This statement in no way comments on the likelihood that commercial partners will be interested in Amarin, or ties this interest to the success of the ANCHOR study. In fact, it leaves an open question as to whether Amarin will even seek additional financing through a commercial partner. Plaintiff has not explained why a statement of this nature would have been materially false or misleading. *See Winer Family Trust*, 503 F.3d at 326 (To state a claim for securities fraud, a plaintiff must "specify each allegedly misleading statement" and "why the statement was misleading."). And, furthermore, based on the facts alleged in the SAC, the Court can see no reason why such a statement might be considered false or misleading.

Thero's statement, on the other hand, is in conformity with Plaintiff's characterization, and clearly predicts that the positive results of the ANCHOR study will stimulate additional interest in Amarin from commercial partners. SAC ¶ 260. However, Plaintiff's assertion that this statement is materially false or misleading is lacking for a number of reasons. First, Thero's statement is a forward looking expression of his opinion. For such a statement to be actionable, Plaintiff would need to allege that Thero did not honestly believe his statement at the time it was made, or that Thero could have had no reasonable basis to make such an assertion. *See City of Edinburgh*, 754 F.3d at 170. Plaintiff does not allege that Thero did not honestly believe that the ANCHOR study results would lead to increased commercial partner interest. Nor does Plaintiff allege that the ANCHOR study was not a success or did not provide positive results. In addition, there is no direct contradiction between Plaintiff's allegation that potential commercial partners would be dissuaded from investing in Amarin based on the regulatory record and Thero's statement. Indeed, under the facts alleged it would be perfectly reasonable for Thero to opine that some potential commercial

partners might be attracted by the ANCHOR results, in spite of the regulatory record. Thus, taking into consideration the allegations as a whole, the Court finds that Plaintiff has failed to allege that Thero's statement had no reasonable basis or was not honestly believed at the time it was delivered. Accordingly, his statement cannot be considered materially false or misleading.

In sum, Plaintiff has failed to state a Section 10(b) claim on the basis of either Amarin or Thero's statements regarding potential future commercial partners, because under the facts alleged, these statements are neither materially false nor misleading.

viii. Claims that Vascepa was Designed to be First-in-Class for the Treatment of High TGs and Statements Regarding the Size of the Anticipated Market for the ANCHOR Indication

Plaintiff alleges that Defendants' statements (1) "that Vascepa was 'designed to be first in class' for the treatment of high triglycerides" and (2) that the anticipated market for the ANCHOR indication was a "36 million patient population" were "materially false or misleading when made, and/or omitted material information necessary to make the statements not misleading under the circumstances in which they were made." SAC ¶ 209(vi), 209(viii). Plaintiff alleges that Defendants made statements to this effect on multiple occasions.[19] However, nowhere in the SAC

[19] Defendants are alleged to have made the statements to this effect on the following occasions: (1) A November 29, 2010 conference call, SAC ¶¶ 217-18, 220; (2) a December 16, 2010 press release, SAC ¶ 224; (3) a March 16, 2011 press release, SAC ¶ 233; (4) an April 18, 2011 press release, SAC ¶ 253; (5) an April 18, 2011 conference call, SAC ¶ 257; (6) a May 10, 2011 conference call, SAC ¶ 269; (7) an August 9, 2011 press release, SAC ¶ 283; (8) an August 10, 2011 earnings call, SAC ¶ 285; (9) a November 7, 2011 press release, SAC ¶¶ 294-95; (10) a November 8, earnings call, SAC ¶ 297; (11) a January 3, 2012 letter to shareholders, SAC ¶ 298; (12) a February 26, 2013 press release, SAC ¶ 349; (13) a February 28, 2013 press release, SAC ¶ 350; (14) a February 28, 2013 conference call, SAC ¶ 352; (15) a May 9, 2013 Press Release, SAC ¶ 357; (16) a May 9, 2013 conference call, SAC ¶ 360; a (17) June 19, 2013 press release, SAC ¶ 367; and (18) an August 8, 2013 press release, SAC ¶¶ 380-81.

does Plaintiff explain why such statements would be materially false or misleading. The PSLRA requires that in addition to specifying each allegedly misleading statement made by the defendant, a plaintiff must also allege "why the statement was misleading." *Winer Family Trust*, 503 F.3d at 326 (construing 15 U.S.C. § 78u-4(b)(1)). Because Plaintiff has failed to explain why these statements were materially false or misleading, these statements cannot form the basis of his Section 10(b) claim.

In sum, because the existence of a materially false or misleading statement is an essential element of a Rule 10b-5 action, and I have found that none of the statements identified by Plaintiff qualify, Plaintiff's Section 10(b) claim is dismissed without prejudice for failure to state a claim.[20]

B. Claims under Section 20(a) of the Exchange Act

In Count Two, Plaintiff alleges that the Individual Defendants violated Section 20(a) of the Exchange Act. "Section 20(a) of the Exchange Act creates a cause of action against individuals who exercise control over a 'controlled person,' including a corporation, who has committed a section 10(b) violation." *City of Edinburgh*, 754 F.3d at 177 (citing 15 U.S.C. § 78t(a)). Section 20(a) liability "is derivative of an underlying violation of Section 10(b) by the controlled person." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013) (quoting *Avaya*, 564 F.3d at 252). Thus, because Plaintiff fails to state a claim under Section 10(b), the Individual Defendants cannot be liable under Section 20(a). *See City of Edinburgh*, 754 F.3d at 177. Therefore, Count Two must also be dismissed without prejudice for failure to state a claim.

[20] Because I have already determined that Plaintiff has failed to plead any materially false or misleading statements, I need not reach the question of whether Plaintiff adequately alleges that Defendants had the necessary scienter to violate Rule 10b-5. Likewise, I need not address Defendants' arguments that the alleged false or misleading statements are inactionable, pursuant to the truth-on-the-market doctrine.

IV. Conclusion

For the foregoing reasons, Defendants' motion to dismiss is granted. The SAC is dismissed without prejudice[21] and this matter shall be marked closed.

Date: April 26, 2016

/s/ Freda L. Wolfson
Freda L. Wolfson
U.S. District Judge

[21] Defendants argue that Plaintiff's claims should be dismissed with prejudice because "[t]his is Plaintiff's third pleading in this case, and his failure to add any new substantive factual allegations at this late stage shows that his claim will never have merit." Defs.' Supp. Br. at 30. However, I am not convinced that any attempt to amend the Complaint by Plaintiff would be futile. Therefore, it is not appropriate to dismiss Plaintiff's claims with prejudice at this juncture.